

REMARKS.

Applicant has submitted, herewith, amendments to the claims which are intended to more particularly point out and distinctly claim the invention. Specifically, applicant has cancelled claims 42-53, the examined claims, and substituted therefore, newly presented claims 63-71. Independent Claim 63 corresponds to cancelled claim 42. By these amendments, applicant has incorporated the limitations of claims 43, 44 and 52 into the independent claim 63.

Thus, Claims 32-41 and 54-71 are currently pending in the application. Claims 32-41 and 54-62 stand withdrawn from consideration as being directed to the non-elected invention. Thus, claims 63-71 are subject to examination. The rejections set forth in the Office action of April 10, 2006 are addressed as they are believed to be applicable to newly presented Claims 63-71.

Thus, applicant believes that the examiner would intend the following rejections as being applicable to the newly presented claims: Claims 63-71 stand rejected under 35 U.S.C. 102(b) as anticipated by Costabile (2001). Claims 63-71 stand rejected under 35 U.S.C. 102(a) as anticipated by Mak et al. (US2002/0182260) Claims 63-71 stand rejected under 35 USC 103(a) as unpatentable over Costabile (2001) in view of Ghosh et al. (924). Claims 63-71 stand rejected under 35 USC 103(a) as unpatentable over Costabile (2001) in view of Schmidt (1989). Claims 63-71 stand rejected under 35 USC 103(a) as unpatentable over Costabile (2001) in view of Sethi et al. (2002).

Applicant herewith submits amendments to the claims which are intended to

further point out and distinctly claim the invention and which are believed to more clearly distinguish the claimed invention from the disclosure of the references relied upon by the Examiner. Applicant respectfully traverses the grounds and basis for the rejections based on prior art for the reasons which follow:

Rejection under 35 USC 102(b):

Rejection over Costabile (2001):

At pages 3-4, the Examiner sets forth the rejection of claims 42,43, 47-49 (presently claims 63-71) under 35 USC 102 (b) as anticipated by Costabile et al. (2001). Applicant would urge that the newly presented claims are not anticipated by the Costabile et al. reference. Applicant would urge that the Examiner may have misconstrued teaching of this reference. Thus, the disclosure referenced as being on page 3983 of Costabile *et al*) to the testing of a specific substance at different concentrations as being more relevant than they really are. The mere comparison of the activities of one specific test substance at different concentrations is quite different from the standardized assay method of the present application, whereby the anti-inflammatory of different samples of (for example) emu oil can be compared and graded in a scientific and quantitative fashion. Costabile does not teach or describe a standardized assay for evaluating different samples of the same substance, particularly using the serial dilution technique now required by claim 63. The experimental results provided in references such as Costabile *et al* provide confirmation that the substance under consideration has the desired anti-inflammatory activity. However, the cited experimental results do not provide a standardized assay

method for comparing the anti-inflammatory activities of different samples of a biological product, such as emu oil.

Since the remaining claims depend from claim 63, the same arguments are equally applicable as it relates to the deficiency of Costabile relative to these claims.

Applicant would urge that anticipation requires the disclosure, in a single prior art reference, of each element of the claim under consideration. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983). Here, the newly presented claims 63-71, include specific limitations which Costabile fails to account for or describe. Thus, with regard to these claims, Costabile fails to disclose every limitation present in the claims and therefore can not reasonably be said to anticipate the claimed invention within the meaning of 35 U.S.C. 102(b).

Thus, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the mentioned claims as unpatentable over Costabile.

Rejection under 35 USC 102(a):

Rejection over Mak et al. (US2002/0182260):

At pages 4-5, the Examiner has rejected claims 42-44 and 47-49 as anticipated by Mak et al. (US2002/0182260). To the extent that the reference is applicable to the newly presented claims to the standardized assay method of the present claims, applicant would urge that this reference fails to teach each limitation of these claims.

Specifically, applicant would note that Mak et al. do not describe or disclose a standardized method for assessing the anti-inflammatory activity of a substance using an

assay which includes a serially repeating step whereby the testing or assay includes the step of repeating the test or assay for the substance by repeating the steps of the assay using a serially reducing amount of said substance (Claim 63) wherein alcohol is used as the diluting agent (Claim 71). Since Mak et al. neither teach or suggest this step or aspect of a standardized assay procedure, the reference fails to anticipate the presently claimed invention.

Thus, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the mentioned claims as unpatentable over Mak et al.

The Rejections Under 35 USC 103(a):

Costabile in view of Ghosh et al.:

At pages 5-7 of the Office Action (OA), the Examiner has set forth the basis for the rejection of currently pending claim 6 as being unpatentable over Costabile (2001) in view of Ghosh et al. ('924).

In rejecting the claims in question, the Examiner acknowledges that Costabile fails to disclose or teach the use in an assay of the type claimed of specific animal or plant oils or extracts thereof. However, the Examiner urges that Ghosh cures this deficiency in teaching emu oil and other animal or plant oils as anti-inflammatory composition.

The Examiner urges that the ordinary artisan would have been motivated to use animal (emu) oil or plant oil in the methods taught by Costabile as a means of control in the experiment involving a novel synthetic polysaturated fatty acid.

What is missing from this analysis is any suggestion to be found in the prior art

that would have suggested the use of the substances disclosed by Ghosh et al. in a standardized assay method of the type claimed. Ghosh would appear to suggest that the substances disclosed were known to have at least some level of anti-inflammatory activity. There is nothing which would suggest the need or desirability to assay these substances using a standardized method as presently claimed. For example there is no teaching or disclosure which would suggest the need or desirability of the control in the experimental process involving novel synthetic polysaturated fatty acids. There also appears to be no explicit direction to isolate polysaturated fatty acids from the substances described by Ghosh.

In addition, applicant would urge that the newly submitted modified claims 63-71 differs more significantly from the disclosure of Costabile for the reasons set forth above relating to the rejection under 35 USC 102 over Costabile.

Thus, the applicant would urge that the references, either taken alone or taken in combination, fail to provide the level of evidence which would reasonably support the conclusion of obviousness reached. Thus, applicant would respectfully urge that the Examiner reconsider the conclusion of obviousness of the subject matter of the newly presented claims 63-71 over Costabile and Ghosh.

Rejection over Costabile in view of Schmidt:

At pages 7-8 of the Office Action (OA), the Examiner has set forth the basis for the rejection of then pending claims 42, 43, and 47-50 as being unpatentable over Costabile (2001) in view of Schmidt (1989).

The Examiner acknowledges that Costabile fails to teach a method wherein the cells are neutrophils and the activity measured is chemotaxis. However, the Examiner urges that Schmidt cures this defect in teaching a method of characterizing the anti-inflammatory activity of fish oil wherein chemotaxis is examined.

The Examiner urges that one of ordinary skill would have been led to combine the two references since both methods are drawn toward characterizing the anti-inflammatory activity of natural oil compounds on various activities of certain types of cells from the immune system. The Examiner attributes the motivation to do so in that one would be motivated to do so in order to obtain a more complete picture of the effects of a compound on the entire immune system.

Applicant respectfully disagrees. There is nothing to be found in the prior art which actually establishes the need or desirability of using the methodology of Schmidt in the method of Costabile. The issue under obviousness is not whether elements **can** be combined but whether one of ordinary skill would be **led**, by something to be found in the prior art, **to do so**. Here, there is nothing in the prior art which would have reasonably suggested or directed one of ordinary skill to make the modification of the process of Costabile necessary to arrive at the claimed standardized assay presently claimed.

In addition, applicant would urge that the newly amended claims differ from Costabile in other ways, as discussed above, which are not taught or disclosed by Schmidt. Thus, the applicant would urge that the references, either taken alone or taken

in combination, fail to provide the level of evidence which would reasonably support the conclusion of obviousness reached.

Therefore, applicant would urge the Examiner to reconsider the basis of this rejection and withdraw the rejection as applicable to the newly presented claims.

Rejection over Costabile in view of Sethi:

At pages 8-10 of the Office Action (OA), the Examiner has set forth the basis for the rejection of then pending claims as being unpatentable over Costabile (2001) in view of Sethi (2002).

Here, the Examiner acknowledges that Costabile fails to teach a method wherein the cells are neutrophils and the measured activity is adherence to endothelial cells or wherein the assay steps are repeated using serially reducing amounts of a substance serially diluted in ethanol. However, the Examiner urges that Sethi cures these deficiencies in teaching a method involving the polyunsaturated fatty acid eicosapentaenoic acid (EPA) and its effects on the adherence of neutrophils to endothelial cells. Sethi is also urged to teach the serial dilution of a sample using ethanol.

The Examiner urges that the combination of the teachings of these two references would have been obvious because both methods are drawn to characterizing the anti-inflammatory activity of polyunsaturated fatty acids on various activities of certain types of cells from the immune system. Further the Examiner urges that the motivation to combine these two references would be to obtain a more complete picture of the effects of a compound on the entire immune system. The use of dilutions in the assay of

Costabile would have been motivated in order to test different concentration ranges in order to determine the most effective dosage.

Applicant would initially note that the Sethi et al. article was published August 15, 2002 which is after applicant's priority date under 35 USC 119 of March 1, 2002. Therefore, this reference does constitute prior art relative to this application within the meaning of 35 USC 102. As the reference is not prior art within the meaning of 35 USC 102, it also can not be used as prior art under 35 USC 103.

Further, as with the previous rejections, there is nothing to be found in the prior art which actually establishes the need or desirability of using the methodology of Sethi et al in the method of Costabile. The issue under obviousness is not whether elements **can** be combined but whether one of ordinary skill would be **led**, by something to be found in the prior art, **to do so**. Here, there is nothing in the prior art which would have reasonably suggested or directed one of ordinary skill to make the modification of the process of Costabile necessary to arrive at the claimed standardized assay presently claimed.

In addition, applicant would urge that the newly amended claims differ from Costabile in other ways, as discussed above, which are not taught or disclosed by Sethi. Thus, the applicant would urge that the references, either taken alone or taken in combination, fail to provide the level of evidence which would reasonably support the conclusion of obviousness reached.

Conclusion

In conclusion, applicant has presented newly amended claims and arguments relating to those rejections set forth in the Office action of April 11, 2006. Applicant, respectfully, requests that the Examiner reconsider these rejections and find all claims allowable.

Should any official at the United States Patent and Trademark Office deem that any further action by the Applicant or Applicant's undersigned representative is desirable and/or necessary, the official is invited to telephone the undersigned at the number set forth below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17 or credit any overpayment, to deposit account No. 503321. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, or otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 503321.

Respectfully submitted,

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